AGAMREE

Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
Variation type II /	C.I HUMAN AND VETERINARY MEDICINAL	11/12/2025		SmPC and PL	Submission of the final report from phase I study

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

EMA/VR/0000290634	PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted Submission of the final report from phase I study SNT-I-VAM-024; this is a randomized, cross-over, open-label study to evaluate the pharmacokinetics, safety and tolerability of vamorolone oral suspension given as a single dose in healthy Chinese adult male subjects.				SNT-I-VAM-024; this is a randomized, cross-over, open-label study to evaluate the pharmacokinetics, safety and tolerability of vamorolone oral suspension given as a single dose in healthy Chinese adult male subjects. Update of SmPC section 5.2 to reflect the results of study SNT-I-VAM-024.
Variation type II / EMA/VR/0000280104	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.6 and 5.3 of the SmPC in order to update information and recommendations regarding pregnancy based on results from a dose range finding embryo-fetal developmental toxicity study of vamorolone by the oral (gavage) route in the female CD-1 IGS mice (study 20496186).	30/10/2025		SmPC	Update of sections 4.6 and 5.3 of the SmPC in order to update information and recommendations regarding pregnancy based on results from a dose range finding embryo-fetal developmental toxicity study of vamorolone by the oral (gavage) route in the female CD-1 IGS mice (study 20496186); the Package Leaflet is updated accordingly.
Variation type IA / EMA/VR/0000308122	This was an application for a group of variations.	28/10/2025	N/A		

	B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.a Up to 10-fold increase compared to the originally approved batch size - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted				
Variation type IB / EMA/VR/0000303155	B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted	22/10/2025	N/A		
Variation type IB / EMA/VR/0000294402	This was an application for a group of variations. B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.f Minor change in the manufacturing process of an aqueous oral suspension - Accepted B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted	01/10/2025	N/A		

	B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Other changes - Accepted B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.e Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for nonsterile medicinal products - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.b Primary packaging site - Accepted B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted				

	B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.b.4 Change in the batch size (including batch size ranges) of the finished product - B.II.b.4.a Up to 10-fold compared to the originally approved batch size - Accepted				
Variation type II / EMA/VR/0000284698	This was an application for a group of variations. C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.13 Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority - Accepted	18/09/2025	N/A		

	A grouped application consisting of: C.I.13: Submission of the final report from study SNT-I-VAM-025. This is a phase I, open-label, single-arm study to evaluate the CYP3A4 induction potential of vamorolone on the pharmacokinetics of midazolam (a sensitive CYP3A4 probe) in healthy subjects. C.I.13: Submission of the final report from study SNT-I-VAM-026. This is a phase I, open-label, randomized, 3-arm, parallel-group,positive- and negative-arm controlled study to evaluate the mineralocorticoid receptor antagonism effect of vamorolone in healthy subjects.				
Variation type IA / EMA/VR/0000286394	This was an application for a group of variations. B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Accepted B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Accepted	25/07/2025	N/A		

	B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.a Tightening of specification limits - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.e Update of the test procedure to comply with the updated general monograph in the Ph. Eur. - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c				

	Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Refused				
Variation type IB / EMA/VR/0000278803	B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.f Minor change in the manufacturing process of an aqueous oral suspension - Accepted	04/07/2025	N/A		
Variation type IB / EMA/VR/0000263794	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z - To provide an updated environmental risk assessment (ERA) report.	21/05/2025	N/A		
Variation type IB / EMA/VR/0000248412	B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.z Other changes - Accepted	26/02/2025	N/A		
PSUR / EMA/PSUR/0000248446	- -				Maintenance
PSUR / EMA/PSUR/0000288222	- -				Maintenance